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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,103	09/15/2006	Yukihiko Mashima	Q96480	9096
23373 7590 04/29/2010 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			EXAMINER SHAW, AMANDA MARIE	
			ART UNIT 1634	PAPER NUMBER
			NOTIFICATION DATE 04/29/2010	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/593,103

Applicant(s)

MASHIMA, YUKIHIKO

Examiner

Amanda Shaw

Art Unit

1634

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/10/2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4, 11-37 and 40-42 is/are pending in the application.
- 4a) Of the above claim(s) 1, 11, 12 and 14-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2, 4, 13, 40-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. This action is in response to the papers filed February 10, 2010. This action is made FINAL.

Claims 1-2, 4, 11-37, and 40-42 are currently pending.

Claims 2, 4, and 13 have been amended.

Claims 40-42 are newly presented.

Claims 1, 11-12, 14-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on June 24, 2009.

Declaration

2. The declaration under 37 CFR 1.132 filed February 10, 2010 is sufficient to overcome the art rejections based upon Ishikawa (J Glaucoma 2004 Vol 13 No 6 pages 466-471).

Withdrawn Rejections

3. The rejection made under 35 USC 112 2nd paragraph in section 4 of the Office Action of September 9, 2009 is withdrawn in view of amendments made to the claims.

The rejection made under 35 USC 112 1st paragraph (enablement) in section 5 of the Office Action of September 9, 2009 is withdrawn in view of amendments made to the claims.

The rejection made under 35 USC 103 in section 6 of the Office Action of September 9, 2009 is withdrawn in view of declaration filed under 37 CFR 1.132.

Claim Rejections - 35 USC § 112 2nd paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The following rejection is necessitated by the amendments made to the claims

Claims 2, 4, 13, and 40-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 4, 13, and 40-42 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step is one that accomplishes the objective of diagnosing or predicting susceptibility to open angle glaucoma. The claims recite two active process steps (obtaining a sample and analyzing a sample). The claims further recite a wherein clause that states "wherein when said subject has at least one polymorphism selected from the group consisting of an adenine at position 462 of the noelin 2 gene, a cytosine at position 1105 of the myocilin gene, and an

adenine at position 412 of the optineurin gene, said subject has or is susceptible to open angle glaucoma". In the instant case this is not equivalent to actually reciting a step of "diagnosing or predicting susceptibility to open angle glaucoma".

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The following is a new rejection necessitated by amendment

Claims 2, 4, 13, and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Umeda (Invest Ophthalmol Vis Sci 2003 Vol 44 E-Abstract 1111) in view of Mukhopadhyay (Molecular Vision 2002: Vol 8 pages 442-448) and Mukhopadhyay (Molecular Vision 2004 Vol 10 pages 304-314).

Regarding Claim 2 Umeda teaches obtaining DNA from 149 patients with various types of glaucoma and 43 normal subjects. Exons 4, 5, 6, and 16 of the Optineurin (OPTN) gene were amplified by PCR and then submitted to direct sequencing. A heterozygous change 412G>A (Thr34Thr) in exon 4 was found in 18 POAG, 4 NTG, 4 SG, 2 CapG, 3 ConG, 3 PACG, and 6 normal patients (abstract). Thus Umeda teaches a method comprising obtaining a biological sample from a subject and analyzing the sample to determine the nucleotide at position 412 of the OPTN gene. Umeda further

teaches that OPTN mutations have been identified as responsible for open angle glaucoma. Thus Umeda teaches a method wherein a subject who has the 412G>A (Thr34Thr) has or is susceptible to open angle glaucoma.

Regarding Claim 4 Umeda teaches a method further comprising analyzing the sample for the presence of at least one other genetic polymorphism associated with open angle glaucoma since Umeda teaches that they also detected the 603T>A (Met98Lys) and 1944G>A (Arg545Gln) mutations of the OPTN gene and both of these have been previously associated with open angle glaucoma (abstract).

Regarding Claim 13 Umeda teaches that the mutations were detected by PCR and direct sequencing (abstract).

Regarding Claims 40-42 Umeda teaches a method wherein said open angle glaucoma is primary open angle glaucoma or normal tension glaucoma since the 412G>A (Thr34Thr) mutation was found in 18 POAG and 4 NTG patients (abstract).

Umeda does not teach a method comprising determining the nucleotide present at position 1105 of the myocilin gene (clm 2).

However Mukhopadhyay (Molecular Vision 2002: Vol 8 pages 442-448) teaches a method wherein DNA was collected from 56 patients with primary open angle glaucoma patients. Mukhopadhyay teaches that the coding sequence of the myocilin (MYOC) gene was amplified by PCR and the PCR products were sequenced (abstract). Thus it is a property of the method of Mukhopadhyay that it determined the nucleotide present at position 1105 of the MYOC gene.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Umeda by additionally determining the determining the nucleotide present at position 1105 of the myocilin gene as suggested by Mukhopadhyay. The prior art of Mukhopadhyay teaches that defects in the myocilin gene have been shown to be associated with primary open angle glaucoma. As such one would be motivated to sequence the MYOC gene in order to determine if the patient had any other mutations that might be associated with open angle glaucoma particularly since early detection results in early treatment which can postpone or prevent loss of vision.

Neither Umeda nor Mukhopadhyay (Molecular Vision 2002: Vol 8 pages 442-448) teach a method comprising determining the nucleotide present at position 462 of the noelin 2 gene (clm 2).

However Mukhopadhyay (Molecular Vision 2004 Vol 10 pages 304-314) teaches that the noelin-2 should be tested as a candidate gene for eye disorders (such as POAG) since it is expressed in the eye and shares olfactomedin domains with MYOC (abstract).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Umeda and Mukhopadhyay (Molecular Vision 2002: Vol 8 pages 442-448) by additionally determining the nucleotide present at position 462 of the noelin 2 gene as suggested by Mukhopadhyay (Molecular Vision 2004 Vol 10 pages 304-314). Based on the teachings of Mukhopadhyay one of skill in the art would have been motivated to sequence all of

the exons of OPTN gene looking for mutations that were associated with eye disorders. By sequencing each of the exons one would have determined the nucleotide present at position 462 of the noelin 2 gene.

Response To Arguments

6. In the response filed March 10, 2010, Applicants traversed the 103 rejection over the combination of Ishikawa in view of Umeda and Mukhopadhyay. It is noted that this rejection has been withdrawn in view of the 132 declaration filed by Applicants, however new are rejections have been presented herein.

The claims are now rejected over Umeda (Invest Ophthalmol Vis Sci 2003 Vol 44 E-Abstract 1111) in view of Mukhopadhyay (Molecular Vision 2002: Vol 8 pages 442-448) and Mukhopadhyay (Molecular Vision 2004 Vol 10 pages 304-314). The prior art references teach that mutations in all three of the genes being claimed have been associated with open angle glaucoma. The prior art references each teach or suggest sequencing these genes to look for mutations that are associated with open angle glaucoma and it is a property of the methods disclosed in these references that one sequence each of the claimed genes would determine the nucleotides present at each of the claimed positions. The fact that the Mukhopadhyay (Molecular Vision 2002: Vol 8 pages 442-448) and Mukhopadhyay (Molecular Vision 2004 Vol 10 pages 304-314) references do not actually teach that there can be an adenine at position 462 of the Noelin gene or a cytosine at position 1105 of the myocilin gene is irrelevant because the claims do not require detecting the variant alleles at these positions. They only require

determining the identity of the nucleotides at each of the positions. Therefore the steps of obtaining and analyzing are obvious over any combination of references that teaches sequencing these three genes.

7. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda M. Shaw whose telephone number is (571) 272-8668. The examiner can normally be reached on Mon-Fri 7:30 TO 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached at 571-272-0731. The fax phone number for

the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda M. Shaw
Examiner
Art Unit 1634

/Stephen Kapushoc/
Primary Examiner, Art Unit 1634